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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/398,854	09/17/1999	HANS BAUMANN	(B&B)-TRI-42	1576

7590 12/13/2004  
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EXAMINER

BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/398,854

Applicant(s)

BAUMANN ET AL.

Examiner

Mark W Bockelman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 08/321,638.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 101***

Claims 11-12 are rejected under 35 U.S.C. 101 because independent claim 11 recite a device inside a patient's body as well as a device outside the patients body which thus positively includes a patient 's body as part of the invention. Such an inclusion is considered impermissible under 35 USC 101 since it would include within its scope the body of a human being. Claiming a human being has long been recognized as non-statutory subject matter. See attached memorandum from former Assistant Secretary and Commisioned Donald Quigg. Applicant should cancel the prohibited claim language in favor of language that defines the invention in terms of an intended use, i.e. as being "adapted to be positioned inside a patient's body" to avoid a 35 USC 101 rejection.

### ***Reissue Applications***

Claims 1-19 are rejected under 35 U.S.C. 251 as being improperly broadened in a reissue application made and sworn to by the assignee *and not the patentee*. A claim is broader in scope than the original claims if it contains within its scope any conceivable product or process which would have infringed the original patent. A claim is broadened if it is broader in any one respect even though it may be narrower in other respects. See MPEP 1410.01 and 37 CFR 1.172.

In the event a pursuance of claim broadening is to be made, in accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 1-19 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

### ***Recapture***

Claims 1-19 rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Pannu v. Storz Instruments Inc.*, 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001); *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

Following the guidelines for determining recapture as set forth in the MPEP beginning at section 1412.02, it is required that the examiner perform a first step of

determining if any broadening of claims exists in the claims presented for reissue. It is clear that both independent reissue claims 1 and 11 have been broadened with respect to their corresponding patented claims by the deletion of the limitation "at least three stable operating states" and replacing the subject matter with limitation "multistable states", which of course may include two or more states, and thus is considered broader in scope. Reissue claim 11 is additionally presented with the deletion of the three operating state positions of the piston member and the substitution thereof the phrase "at least two", which is second point of broadening of reissue claim 11 with respect to patented claim 11. It is also clear that applicant's newly presented claims 13-19 have been broaden in many additional respects compared to corresponding patented claim 11.

Newly present reissue claim 13 defines an apparatus and is therefore compared to the corresponding apparatus claim 11 of applicant's patent. Most of the subject matter found in patented claim 11 has no corresponding structure presented in reissue claim 13. Among the subject matter that is absent is that of the recitation of a service device specified in patented claim 11 to be positioned outside the patient's body for switching the implantable flow-limiting device to various stable states. As the result of this omission, reissue claim 13 is considered to be a subcombination claim vis-à-vis the patented claim 11 in that claim 13 only defines an implantable flow-limiting device whereas patented claim 11 recites a combination service device and implantable flow limiting device. The limitations of subcombination reissue claim 13 are not comparable to the structure of the patented combination claim 11 and thus define an invention

differing in category to the original patented, and would thus cover different subject matter under infringement tests as described in MPEP 1412.03. It is therefore concluded to be broadened in at least in this one respect.

As noted above, claim 13 also has omissions in terms of the implantable flow-limiting device that result in broadening for purposes of recapture determination. Claim 13 omits any structure comparable to the switchable three stable state flow-limiting device of claim 11. Also omitted are the plurality of throttle paths that are arranged to follow the flow limiting device and the ability to switch the flow of fluids from one throttle pathway to another using the service device. Also omitted are the specifics of the flow limiting device in terms of the recited piston, its three positional operating states and the specifics of the chamber in which it is displaceable, including the lateral intake as well as two outlets at opposing ends faces.

According to MPEP1412.02, the second step of the three step test for determining whether improper recapture of claimed subject matter exists in a reissue application is to determine whether the broader aspects of the reissue claim relate to surrendered subject matter. With respect to claims 1 and 11, it is clear that the phrase "at least three" which limits the number of the operational states of the flow-limiting device and which is now proposed be deleted and replaced by the term "multistable" does in fact relate to surrendered subject matter. Evidence for this conclusion can be found in the amendment to the claims in the parent patent file filed on March 18, 1996. In that amendment, the limitation in claim 1 of a flow limiting means, as well as limitation

term "multistable" in amended claim 12 were cancelled and replaced with the phrase "at least three" (operational states). The phrase was then later argued on page 7 of that amendment to be a distinguishing feature over the then applied reference to Ellinwood, Jr. The three positions of the piston valve was included in that argument. Clearly, the subject matter of "at least three" operational states as well as the three piston positions are seemed surrender subject matter in accordance with MPEP 1412.02

With respect to reissue claim 13 as compared to patented claim 11, Claim 11 as patented was the culmination of objected subject matter presented in claims 12 –16 in the amendment filed March 18, 1996 that was not contested, but rather represented in amended form in the amendment filed December 14, 1996. The subject matter was thus surrendered. In addition, patented claims 1 and 11 were presented in their allowed form in the amendment of December 14, 2004 as were claims 1 and 21 with the inclusion of a service device, placed outside the body for transmitting power to the implantable device. The inclusion was argued to be a patentable feature and to distinguish over the Ellinwood reference which had a battery inside the pump member for operating the device rather than an energy transmitting configuration associated with a service member

The third step of recapture determination is to determine whether the reissue claims are materially narrowed in other respects to compensate for the broadening in the area of surrender to avoid the recapture rule. Considering first reissue claims 1 and

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11. During the prosecution of the 5,667,504 patent, claims 1 and 12, as amended in the response dated March 18, 1996, which ultimately resulted in claims 1 and 11 of the allowed patent, the phrase "at least three stable operating states" was added to each of these claims and on page 9 of that response applicant, argued that the inclusion of a valve having at least three stable operating positional states defined the claims over the Ellinwood reference. The previous state of claim 12, used the term "multi-stable state" which applicant now attempts to recapture. Thus applicant is not attempting to replace the "key limitation" of the claim with a broader version of the "key limitation" as was determined to be permissible broadening in *Pannu v. Storz Instruments Inc.*

(MPEP1412.02 C.), but instead, applicant is attempting to return to the original limitation that was replaced by the "key limitation". Thus, the examiner concludes that for reissue claims 1 and 11, applicant's attempt to broaden the claims by adding replacing the "at least three" limitation with "multi-stable" constitutes impermissible recapture. Further with respect to claim 11, the valve member that was argued to have at least three stable states in the response of March 18, 1996 is the same element that is later recited in patented claim 11 as a "piston" with three stable states. Thus applicant's arguments concerning the valve, also applied to the piston and applicant's amendment in reissue claim 11 to replace "three" with "at least two" go hand in hand with the same grounds for denying the reissue claim amendments to claims 1 and 11 based upon recapture.

With respect to claim 13, as noted above, applicant has presented a much broader claim with respect to its counterpart patent claim 11 and in doing so has

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attempted impermissible recapture of claim subject matter. Most notably, applicant has eliminated the service device that is "adapted" to be positioned outside the body and which is the sole source of power for powering the implanted device. Applicant has also eliminated the three state positionable valve member that was argued in the response of March 18, 1996 that is noted above. Applicant neither claims the valve or a three state flow controlling member, both of which (i.e a three state positionable valve member) were argued (see MPEP 1412.02 C 2a.) as a patentable feature and cannot not be eliminated from the claims without incurring impermissible recapture. Similarly, the service device that was particularly pointed out as a distinction in its extracorporeal usage in the amendment of 12-14-1996 cannot be deleted. It is noted that applicant has added a receiver for receiving radio frequency signals to the claims however the receiver does not constitute the same element as the service device and may be considered an element that may or may not require a service device. Thus while applicant may be narrowing the reissue claim (13) with respect to receiver, he is still eliminating a "key limitation" that was added to the claim and argued to place 08/321,638 application in condition for allowance. This is the same scenario explained in MPEP 1412.02 C 2(a) that would constitute recapture.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13 –18 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorman et al. USPN 4,718,893. Dorman et al teaches an implantable pump member (e.g. figure 5) with a fluid reservoir 22 and a passive regulator assembly comprising plate 32 and first valve member 40 passive regulator assembly that is adjustable for regulating fluid flow from the reservoir. An electromechanical controller 55 (column 7 lines 40-45) can be used to change the force pressure on the diaphragm member for controlling the flow rate as seen in the equations in column 9 line 26. An external service member 56 that may use the same RF transmitting power disclosed in patents 4,373,527 and 4,146,029 may be used to change the force settings when power is transmitted to the implantable device and receive by the receiver to control the force applied. (column 7 lines 50-60). The examiner considers the flow restrictor to be either the passageway associated with the valve, or the restrictor 66 that is “operatively coupled” to the valve through the housing and tubing. A second valve member 41 would constitute a plurality of valves.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorman et al USPN 4,718, 893 in view of Reinicke USPN 4,604,090. Applicant differs from Dorman et al. in reciting a sensor that may determine the amount of fluid remaining in the reservoir upon telemetric interrogation. Reinicke teaches the benefits of providing such sensor information ( see column 2 lines 48-53) for providing fluid level information upon request. To have provided the Dorman et al reference with such a feature to indicate to the health provider information regarding the need for more medicament would have been obvious to one of ordinary skill in the art.

Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,667,504 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272 -4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

December 9, 2004

**MARK BOCKELMAN**  
**PRIMARY EXAMINER**

A decision by the Board of Patent Appeals and Interferences in Ex parte Allen, \_\_\_ USPQ \_\_\_ (Bd. App. & Int. April 3, 1987), held that claimed polyploid oysters are nonnaturally occurring manufactures or compositions of matter within the meaning of 35 U.S.C. 101. The Board relied upon the opinion of the Supreme Court in Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980) as it had done in Ex parte Hibberd, 227 USPQ 443 (Bd. App. & Int., 1985), as controlling authority that Congress intended statutory subject matter to "include anything under the sun that is made by man." The Patent and Trademark Office now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101.

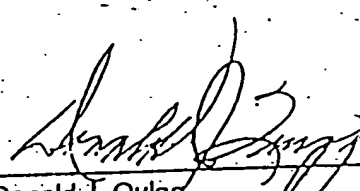
The Board's decision does not affect the principle and practice that products found in nature will not be considered to be patentable subject matter under 35 U.S.C. 101 and/or 102. An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law. See e.g. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 76 USPQ 280 (1948); American Fruit Growers v. Brogdex, 283 U.S. 1, 8 USPQ 131 (1931); Ex parte Grayson, 51 USPQ 413 (Bd. App. 1941).

A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation "non-human" to avoid this ground of rejection. The use of a negative limitation to define the metes and bounds of the claimed subject matter is a permissible form of expression. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Accordingly, the Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals. To the extent that the claimed subject matter is directed to a non-human "nonnaturally occurring manufacture or composition of matter - a product of human ingenuity" (Diamond v. Chakrabarty), such claims will not be rejected under 35 U.S.C. 101 as being directed to nonstatutory subject matter.

**BEST AVAILABLE COPY**

Date 4-7-87

  
Donald J. Quigg  
Assistant Secretary and Commissioner  
of Patents and Trademarks